

Applicant(s) : Guangwen WEI, et al.
U.S. Serial No.: 10/650,365
Filed : August 28, 2003
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REMARKS

The specification was amended in order to correct typographical errors, conform to proper trademark usage and SEQ ID NO form.

On Page 1, lines 25 and 29 of the specification, rSIFN-co was changed to IFN-con in order to properly characterize the invention of U.S. Patent Nos. 4,695,623 and 4,897,471 (See EXHIBIT B column 33 "Example 9" of the '623 and '471 patents).

On page 1, line 32 rSIFN-co was changed to IFN-con in order to correctly address the invention disclosed in U.S. Patent No. 5,372,808 (See EXHIBIT C column 3 of the '808 patent).

On Page 1, lines 33-34 rSIFN-co was changed to consensus interferon in order to correctly characterize the invention disclosed in Chinese Patent No. 97193506.8 (corresponding to CN1217660A, see EXHIBIT D translated abstract).

On page 1, line 36 was rSIFN-co was changed to recombinant human consensus interferon- α to correctly address the invention disclosed in Chinese Patent No. 98114663.5 (corresponding to CN1062565C, see EXHIBIT E translated abstract).

On page 2, line 1 rSIFN-co was changed to INFERGEN[®] (interferon alfacon-1) to correctly name the interferon produced by Amgen.

The amendments to pages 4-5, 14-17, 20, 29, 32, 37-39, and 45 were made to overcome the Examiner's objection to the trademark usage of INFERGEN[®] and the form of SEQ ID NO.

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Accordingly, there is no issue of new matter because the subject matter was already incorporated by reference in the aforementioned patents publications and applicants respectfully request the entry of this Amendment to the Specification.

Claims 29 to 37 are pending in this Application. By this Amendment, applicants have hereinabove cancelled claims 29 to 37 without prejudice to applicants' rights to pursue the subject matters in a further application. Applicants add new claims 38 to 47. Claim 38 corresponds to cancelled claim 29. Claim 39 corresponds to cancelled claim 29. Claim 40 corresponds to claim 30. Claim 41 corresponds to claim 31. Claim 42 corresponds to claim 32. Claim 43 corresponds to claim 33. Claim 44 corresponds to claim 34. Claim 45 corresponds to claim 35. Claim 46 corresponds to claim 36. Claim 47 corresponds to claim 37.

Accordingly, there is no issue of new matter and applicants respectfully request the entry of this Amendment. Upon entry, claims 38 to 47 will be pending and under examination.

The following numbering of the REMARKS corresponds to the Examiner's rejections/objections in the Final Office Action dated March 20, 2006.

Specification

3. The Examiner to whom this Application is assigned indicated that this application is noncompliant with sequence disclosure rules. The Specification has been amended above in order to provide SEQ ID numbers to the polypeptides on pages 17 and 20-21. Claim 29 which the Examiner claimed lacked proper format for reporting the sequence ID number has been deleted.

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Applicants believe that the amended specification fully complies with the sequence disclosure requirements and format.

Information Disclosure Statement (IDS)

4. The Examiner was unable to fully consider references in a foreign language because only translated abstracts were provided. Applicant will review references and procure translations where necessary.

Claim Rejections - 35 USC § 112, second paragraph

8. The Examiner rejected claims 29-37 as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention ... with respect to Applicants' recitation of 'super-compound interferon'."

In response, applicants respectfully traverse the above ground of rejection.

On page 6 (1st paragraph) of the Specification, applicants describe the recombinant super-compound interferon as a protein with same primary sequence as a "regular" interferon but different efficacies due to changed spatial configuration. On page 6 (5th paragraph), applicants say this structural change is caused by changes in the production process.

The Examiner also rejected the term "changed spatial configuration and improved efficacy" in claim 1 (corresponding to pending claim 38) as being undefined in the specification. The changed spatial configuration is demonstrated in the

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Figure 6 Circular Dichroism Spectra which shows that two proteins (rSIFN-co and Infergen® (interferon alfacon-1)) with the same primary sequence produced by different methods have changed secondary and tertiary structures. Improved efficacy is shown in the Tables where the accumulated inhibition rates of rSIFN-co to Infergen® (interferon alfacon-1) are shown.

9. The Examiner rejected claim 23 because the term "suitable carrier" was held to be vague and indefinite. The currently amended composition claim no longer contains this term.

Claim Rejections - 35 USC § 102

10. The Examiner rejected claims 29-31 and 34-36 based upon Day et al. because claim 29 was directed to a nucleotide sequence. Claim 29 has been deleted. The corresponding new claim 38 is not anticipated by Day et al because Day et al. describe a murine sequence where the primary sequence was changed in order to alter the interferon's specific activity. The present claim does not teach a change in amino acid sequence, but a change in production methods to produce an interferon with changed secondary and tertiary structure resulting in increased efficacy.

The changed spatial configuration is demonstrated in the Figure 6 Circular Dichroism Spectra which shows that two proteins (rSIFN-co and Infergen® (interferon alfacon-1)) with the same primary sequence produced by different methods have changed secondary and tertiary structures.

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Claim Rejections - 35 USC § 103

11. The Examiner rejected claims 32 and 37 as being unpatentable over Day et al. in light of Olsen et al. (U.S. Patent No. 6,114,145) and Nasoff et al. (1999). As described above, Day et al. do not anticipate the currently amended claims because Day et al. teach a change to the primary sequence of the protein whereas the present invention teaches a change to spatial configuration due to production methods and not to amino acid sequence. Therefore, there can be no obviousness objection combining Day et al. with other references.

New Objections and Rejections

12. The Examiner indicated that the trademark INFERGEN® was not capitalized throughout the application and it was not accompanied by generic terminology. The Specification including the Tables have been amended above in order to comply with MPEP § 608.01(v). Applicants believe that the amended Specification fully complies with the rules concerning trademark usage.

13. The Examiner indicated that the disclosure contained an embedded hyperlink and/or other form of browser-executable code. Applicants deleted the embedded hyperlink and/or other form of browser-executable code contained on page 4 of the Specification in order to comply with MPEP § 608.01. Applicants believe that the amended Specification fully complies with the rules concerning hyperlinks and/or other forms of browser-executable code.

14. The Examiner indicated that the reference to U.S. Patent Nos. 4,695,623 and 4,897,471 in claim 29 was an improper

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incorporation by reference. Applicants have deleted claim 29. In corresponding claim 38, the interferon is described by name and there is no need to incorporate previous patents by reference.

14. The Examiner indicated that Claim 29 was objected to because of the incorrect format of "SEQ ID NO" was used. This claim has been deleted and the corresponding claim 38 does not contain a sequence ID number. The proper form was used in new claim 39.

15. The Examiner objected to Claims 34 and 36 because they were dependent upon cancelled Claim 1. Claims 34 and 36 were cancelled and the corresponding new claims were drafted to depend upon the correct new claim.

Claim Rejections - 35 USC § 112, second paragraph

16a. The Examiner objected to the lack of antecedent basis for the limitation "interferon" in claim 30. Claim 30 has been deleted, removing the basis for this objection.

16b. The Examiner rejected Claim 29 because the interferon polypeptide was being defined by a nucleotide sequence of SEQ ID NO:1. Claim 29 was deleted.

Therefore, applicants respectfully request the reconsideration and withdrawal of this ground of these rejections.

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Conclusion

Applicants maintain all the grounds raised in the March 20, 2006 Office Action have been addressed and earnestly urge the Examiner to render favorable action for the claimed invention.

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai-Kit Chan
Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant(s)
Law Offices of
Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, New York 11357
Tel: (718) 799-1000
Fax: (718) 357-8615
E-mail: chank@kitchanlaw.com

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Fax No.: (703) 872-9306	
on the date shown below.	
<u>Albert Wai-Kit Chan</u> Albert Wai-Kit Chan Reg. No. 36,479	4/12/06 Date